REMARKS

In the Office Action mailed September 30, 2010, all pending claims 1-5, 7-8, 15-19 and 21-22 stand rejected under 35 U.S.C. § 112, first paragraph, and under 35 U.S.C. § 103(a) as being unpatentable over Reiss (USP 5,512,057) in view of Holsheimer (US 5,643,330). Applicant has reviewed the cited art and the Examiner's comments, and requests favorable reconsideration in view of the following remarks.

Enclosed with this response is a Declaration under 37 CFR § 1.132 of Thomas L. Yearwood, MD, PhD ("Yearwood Declaration"). The Yearwood Declaration is referenced below.

I. Declaration under 37 CFR § 1.132 of William Carroll filed on March 10, 2010

A. There is no support for Reiss being "capable of achieving the same depth of penetration" as the present invention

The Examiner stated that the Declaration under 37 CFR § 1.132 of William Carroll filed on March 10, 2010 ("Carroll Declaration") "fails to provide any indication that the achieved beat frequency signal being configured to achieve deeper penetration levels is the result of implanted electrodes," and "[t]herefore, Examiner considers that Reiss, which discloses interferential stimulation, to also be capable of achieving the same depth of penetration". (*Office Action*, 9.30.10, p. 3). The Examiner's conclusion is incorrect and is not supported by any factual basis.

First, the study referenced in the Carroll Declaration involved implanted electrodes and resulted in a beat frequency signal with deeper penetration levels than previously observed. Implantation of the electrodes was at least one direct cause for these results. (*See*, e.g., Carroll Declaration, ¶ 23).

Second, the study referenced in the Carroll Declaration compared the stimulation effects created by the claimed invention to stimulation effects created by applying stimulation using

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conventional surface electrodes, as described in Reiss. (*See*, e.g., Carroll Declaration, ¶ 23-24). Electricity follows a path of least resistance, and applying stimulation on the surface of the skin using surface electrodes does not allow for effective stimulation through the vertebrae. *Id.* Accordingly, it would be impractical to attempt to achieve the stimulation effects seen in the results of the study in Exhibit B of the Carroll Declaration using surface stimulation as in Reiss because it would be highly likely that tissue damage and pain would be caused in the patient when attempting the test. *Id.* Moreover, if current is simply increased, the effect is to spread stimulation through the CSF causing pain. (Carroll Declaration, ¶ 12).

Third, the Examiner has provided no factual support for the conclusion that Reiss is "capable of achieving the same depth of penetration". A rejection including an unsupported conclusory statement is not given any weight. (MPEP § 2142). Whether the Carroll Declaration provides an indication that the achieved beat frequency signal being configured to achieve deeper penetration levels is the result of implanted electrodes has nothing to do with whether Reiss is capable of achieving the same depth of penetration.

B. The Carroll Declaration does not narrow the scope of the invention

The Examiner further stated that Exhibit B to the Carroll Declaration relates to electrodes implanted directly on the Gracile nucleus and directly within the pyramidal tract. The Examiner considered this to "have sufficiently narrowed the scope of the invention, as the electrodes are not simply implanted within the Dura matter in the epidural space." (*Office Action*, 9.30.10, p. 3). Applicant has explained that the Carroll Declaration does not narrow the scope of the invention. The study in Exhibit B included an experimental setup as follows:

> (a) Two pairs of stimulation electrodes (bipolar stimulation, 4 electrodes in total) **were placed epidurally** (to a dura mater in an epidural space) on the spinal cord in two configurations; (i) a crossed and (ii) a parallel configuration (*See*, e.g., Figures 1 and 2 of Exhibit B).

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> (b) Recording microelectrodes were inserted in the Gracile nucleus and the Pyramid tract in the brainstem (*See*, e.g., Figure 1 of Exhibit B). The recording electrodes do not provide stimulation to the Gracile nucleus and the Pyramid tract. Simultaneous recordings from the Gacile nucleus and the Pyramid in the brainstem render easy comparison of the effect of stimulation. (Exhibit B, "Project Outlines").

The electrodes referred to by the Examiner (placed on the Gracile nucleus and pyramidal tract) are the recording electrodes. On the other hand, the stimulation electrodes were placed epidurally. (*See* Figure 1 of Exh. B to the Carroll Declaration). Dr. Yearwood's opinion of this experimental setup further supports this interpretation. (Yearwood Declaration, ¶ 22).

II. Response to Rejection of Claims under 35 U.S.C. § 112

Claims 1-5, 7-8, 15-19 and 21-22 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner stated that the written specification, as originally filed, does not provide support for the limitation "and wherein a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers". The Examiner stated that the specification "makes no mention of the beat frequency signal being configured to avoid remaining in and shunting through CSF proximate to the subject's spinal cord." (*Office Action*, 9.30.10, p. 4).

Support for the claim limitation can be found, for example, within the combination of material on page 2 lines 11-21, page 3 lines 15-23, and page 6, lines 15-20. In the Office Action mailed September 30, 2010, the Examiner indicated that none of these sections describes the entirety of the claim limitation. However, Applicant submits that the patent application in its

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entirety supports the claim limitation, and thus, it is a combination of all of these sections (and the application as a whole), in one example, that support the claim limitation.

In addition, enclosed with this response is a Declaration under 37 CFR § 1.132 of Thomas L. Yearwood, MD, PhD. Dr. Yearwood has been a practicing doctor for 28 years, and has been the primary implanting physician on over 2,000 Intraspinal neurostimulator devices. (Yearwood Declaration, ¶ 1-2). Opinion testimony which purports to state that a particular feature or limitation of a claim is disclosed in an application and which explains the underlying factual basis for the opinion must be considered (MPEP 716.09).

Dr. Yearwood reviewed the present application, and in his opinion, the patent application describes "an electrical stimulator for the treatment of intractable pain syndromes that includes implantable electrodes implanted to a dura mater proximate to a subject's spinal cord, and interferential stimulation is used to produce a beat frequency signal such that a majority of the beat frequency signal is directionally controlled to avoid stimulating adjacent and/or inappropriate neuronal targets within the spinal canal, thereby creating a far more efficacious neurostimulation field in the treatment of pain". (Yearwood Declaration, ¶ 8).

In sum, in Dr. Yearwood's opinion, based on the entirety of the disclosure in the patent application, the patent application describes an electrical stimulator that uses interferential current provided via implantable electrodes to produce a beat frequency signal such that a majority of the beat frequency signal is directionally distributed and controlled to avoid remaining in and shunting through the cerebrospinal fluid proximate to the subject's spinal cord. (Yearwood Declaration, ¶ 20).

Thus, Dr. Yearwood (one of considerable experience in the field of implantation therapy), has provided an opinion that the specification, as originally filed, fully supports the

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claim limitation. In addition, any information that is read into the specification to supplement an understanding of the claim limitation would have been known to those of ordinary skill in the art, as shown for example, by Dr. Yearwood's understanding. (*See*, *e.g.*, MPEP 716.09).

Example aspects of support for the claim limitation based on Dr. Yearwood's opinion are highlighted below. The Examiner is referred to the enclosed Declaration under 37 CFR § 1.132 of Thomas L. Yearwood, MD, PhD in its entirety as a whole for further explanation.

Applicant requests withdraw of the rejection under 35 U.S.C. § 112.

A. "directionally distributed"

The patent application describes that an effective area of stimulation is controlled by the quantity of electrodes, positioning of the electrodes and electrode cross pattern orientation. (Abstract). In Dr. Yearwood's opinion, based on this disclosure, the beat frequency signal can be directionally controlled. (Yearwood Declaration, ¶ 9).

The published patent application describes that in traditional SCS stimulation, the electrodes are normally attached to the dura mater in the epidural space, and most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column. [¶0006]. In Dr. Yearwood's opinion, based on this disclosure, traditional SCS stimulation without the use of interferential currents has limited application because of the spread of the stimulating electrical field within the CSF as intensity of stimulation increases. This is due to the highly conductive nature of the CSF as compared to the less conductive nature of the spinal cord tissue itself. Thus, neurostimulation without interferential current capability is "amplitude limited" to a relatively narrow surface area of the spinal cord. Frequently, patient satisfaction with the electrical stimulation is compromised by the recruitment of adjacent

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neuronal structures that, when activated, can create discomfort, motor contractions, and outright pain. Thus, the efficacy of the therapy is limited. (Yearwood Declaration, ¶ 11).

The patent application describes that in traditional SCS stimulation, the electrodes are normally attached to the dura mater in the epidural space, and most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column. [¶0006]. The patent application also states that providing an interferential component to the electrode array of the SCS allows the crossing of the two signals wherein the resultant additive effect of the beat frequency produces deeper penetration of the signal and a higher resultant amplitude at the stimulation site, and that the interferential current would recruit larger numbers of dorsal column fibers and provide greater levels of pain relief and benefit to intractable pain patients. [¶0006]. In Dr. Yearwood's opinion, based on this disclosure, using an electrical stimulator that includes electrodes implanted upon the dura mater with interferential currents produces a beat frequency signal that has deeper penetration than that possible using traditional SCS stimulation, and a majority of the beat frequency signal can be more precisely controlled in terms of direction and depth of tissue penetration proximate to the subject's spinal cord. (Yearwood Declaration, ¶ 12). Thus, interferential current would recruit larger numbers of dorsal column fibers and potentially provide greater levels of pain relief and benefit to intractable pain patients. (*Id*).

The patent application describes that multiple target areas of the spinal cord can be treated depending upon the quantity and placement of the first and second pairs of electrodes, and by modulating the amplitudes of the outputs of the first and second circuits as shown in Figure 3. [¶0020]. In Dr. Yearwood's opinion, to target specific areas of the spinal cord using

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modulation of the circuit outputs, the resultant beat frequency signal would be directionally controlled and/or depths of penetration are controlled. (Yearwood Declaration, ¶ 17).

The patent application describes that it has been shown that when the first and second circuits intersect at 90°, the maximum resultant amplitude and the deepest level of modulation is half-way between the two circuits as illustrated in Figure 2. [¶0020]. In Dr. Yearwood's opinion, to target specific areas of the spinal cord using modulation of the circuit outputs, the resultant beat frequency signal would be directionally distributed and controlled three-dimensionally. (Yearwood Declaration, ¶ 19).

B. "avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord"

Further based on the disclosure in paragraph 0006 of the published patent application, in Dr. Yearwood's opinion, providing an interferential component to the electrode array of the SCS allows the crossing of the two signals such that the resultant additive effect of the beat frequency produces deeper penetration of the signal and a higher resultant amplitude at the stimulation site because only sub-threshold signals, of minimal biological consequence, remain in or shunt through the CSF. (Yearwood Declaration, ¶ 13).

The patent application describes that using Interferential current in SCS provides for improved directional control and depth of penetration of the beat frequency signal in comparison to other stimulation techniques. [¶0008]. In Dr. Yearwood's opinion, by generating the beat frequency signal, the resultant additive signal is directionally controlled to avoid cerebrospinal fluid proximate to the subject's spinal cord. (Yearwood Declaration, ¶ 15).

In Dr. Yearwood's opinion, the patent application describes that modulating the outputs of the first and second circuits increases the area of the targeted stimulation, and that by enabling control of the depth of modulation, a beat frequency signal can be distributed and controlled to

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avoid neurostimulation of clinically inappropriate neuronal tracts proximate to the subject's spinal cord. (Yearwood Declaration, ¶ 18).

C. "thereby recruiting dorsal column fibers"

The patent application describes that in traditional SCS stimulation, the electrodes are normally attached to the dura mater in the epidural space, and most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column. [¶0006]. The patent application also states that providing an interferential component to the electrode array of the SCS allows the crossing of the two signals wherein the resultant additive effect of the beat frequency produces deeper penetration of the signal and a higher resultant amplitude at the stimulation site, and that the interferential current would recruit larger numbers of dorsal column fibers and provide greater levels of pain relief and benefit to intractable pain patients. [¶0006]. In Dr. Yearwood's opinion, based on this disclosure, using an electrical stimulator that includes electrodes implanted upon the dura mater with interferential currents produces a beat frequency signal that has deeper penetration than that possible using traditional SCS stimulation, and a majority of the beat frequency signal can be more precisely controlled in terms of direction and depth of tissue penetration proximate to the subject's spinal cord. (Yearwood Declaration, ¶ 12). Thus, interferential current would recruit larger numbers of dorsal column fibers and potentially provide greater levels of pain relief and benefit to intractable pain patients. (*Id*).

The patent application describes that an Interferential current in SCS recruits larger numbers of dorsal column fibers and provides greater levels of pain relief in comparison to other SCS techniques. [¶0018]. In Dr. Yearwood's opinion, as a result of recruiting larger numbers of dorsal column fibers by using Interferential current and by generating a beat frequency signal,

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the patients could potentially experience greater levels of pain relief. (Yearwood Declaration, ¶ 16).

III. Response to Rejection of Claims under 35 U.S.C. § 103

Claims 1-5, 7-8, 15-19 and 21-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Reiss in view of Holsheimer. Applicant asserts that the combination of references does not teach all aspects of the independent claims, and traverses the rejection by way of the Declaration under 37 CFR § 1.132 of William Carroll filed on March 10, 2010, and the Declaration under 37 CFR § 1.132 of Thomas L. Yearwood, MD, PhD (enclosed with the present response).

"An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness." (MPEP § 716.02(e)). Applicant is not required to compare the claimed invention with subject matter that does not exist. (MPEP § 716.02(e)(III)). Requiring Applicant to compare a claimed invention with that suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention." *In re Chapman*, 357 F.2d 418, 422 (CCPA 1966). (MPEP § 716.02(e)(III)). Below, Applicant compares the claimed invention with the cited Holsheimer and Reiss references, and demonstrates that the unexpected results are sufficient to rebut the present obviousness claim rejections.

A. Declaration under 37 CFR § 1.132 of William Carroll filed on March 10, 2010

As explained in the Carroll Declaration, a study was performed by the Neuronano Lund Research Center University in Sweden to determine stimulation effects created by an electrical stimulator that embodies the claimed invention. (*See* Exhibit B to the Carroll Declaration). The

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study compared stimulation effects created by the claimed invention to stimulation effects created by a conventional electrical stimulator, as described in the Holsheimer reference. The results of the study demonstrate that the activation thresholds in the dorsal column are significantly lower when using interferential current stimulation of the present invention than when using conventional stimulation as in Holsheimer. Furthermore, the same kind of results were obtained regardless of whether the conventional stimulation was performed in the parallel or crossed configuration. (*See*, e.g., Carroll Declaration, para. 19-20). More specifically, the activation thresholds were reduced by about 50% using interferential current stimulation of the present invention in either the parallel or crossed configuration. (*See*, e.g., Carroll Declaration, para. 19-20). Further, using conventional stimulation as in Holsheimer may spread stimulation through the cerebrospinal conductive fluid within the spinal cord causing chest and thoracic pain. (*See*, e.g., Exhibit A to the Carroll Declaration). In Holsheimer, most of the current distribution remains in the cerebrospinal fluid (CSF) and does not project deeply into the dorsal column to relieve pain, in contrast to the present invention. (Specification, p. 2).

The study also compared the stimulation effects created by the claimed invention to stimulation effects created by applying stimulation using conventional surface electrodes, as described in Reiss. (*See*, e.g., Carroll Declaration, para. 23-24). Electricity follows a path of least resistance, and applying stimulation on the surface of the skin using surface electrodes does not allow for effective stimulation through the vertebrae. *Id.* Accordingly, it would be impractical to attempt to achieve the stimulation effects seen in the results of the study in Exhibit B of the Carroll Declaration using surface stimulation as in Reiss because it would be highly likely that tissue damage and pain would be caused in the patient. *Id.*

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Using the interferential implantable electrode configuration of the present application enables for treatment of pain that cannot be effectively treated by either of the systems in Holsheimer or Reiss. Using the interferential implantable electrode configuration of the present application, interferential current recruits large numbers of dorsal column fibers and provides much greater levels of pain relief and benefit to intractable pain patients (Specification, p. 2), and enables "a majority of the at least one beat frequency signal [to be] directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." (claim 1).

The different results achieved between the present application and either Holsheimer or Reiss are a dramatic improvement and are appropriately classified as a difference in kind, rather than one of degree so as to be evidence sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02). Moreover, the results demonstrated by the study in Exhibit B to the Carroll Declaration are of a significant, practical advantage sufficient to rebut a *prima facie* case of obviousness. (MPEP § 716.02(a)(I)). Enabling for effective treatment of pain through stimulation of the dorsal column without the risks present in the systems in Holsheimer and Reiss (the risks in Reiss are so high as to prevent a practical application of Reiss for treatment) is significant for the population of patients with intractable pain.

B. Declaration under 37 CFR § 1.132 of Thomas L. Yearwood, MD, PhD

1. *Holsheimer*

When using the apparatus described in Holsheimer, most of the pulse applied by the electrode stimulators would remain in the CSF, as shown in Figures 8, 11, 13 and 15, which results from using electrodes with a large contact separation – larger than the thickness of the

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dorsal cerebrospinal fluid layer. (Holsheimer; col. 5, lines 62-67; col. 6, lines 1-9; *See* also Fig 4A). (Yearwood Declaration, ¶ 23).

When using the apparatus described in Holsheimer, the signals cannot be directionally controlled into the spinal cord, but rather, signals are timed such that a field is generated for the recruited area only along the surface of the spinal cord. (Holsheimer; col. 6, lines 30-35). (Yearwood Declaration, ¶ 24). Holsheimer describes a system in which a field is generated that does not project into the spinal cord. (Holsheimer; col. 6 lines 30-35). (Yearwood Declaration, ¶ 26).

Using the apparatus described in Holsheimer with interferential currents (quadripolar stimulation with the electrodes configured in a criss-cross array) **would not be possible** because the action potential field that Holsheimer's apparatus generates is dependent upon configuring the electrodes in a transverse plane (Holsheimer; col. 6, lines 52-55); (in contrast to configuring the electrodes in a sagittal plane, as shown in Fig. 3 of the present application). (Yearwood Declaration, ¶ 25).

2. *Reiss*

One of ordinary skill in the art would not modify the system in Reiss with electrodes implanted upon the dura mater as described by Holsehiemer because Reiss is not used for dorsal column stimulation, and thus, implanting the electrodes in Reiss upon the dura matter is illogical. (Yearwood Declaration, ¶ 27). In particular, Reiss is directed to surface stimulation, and thus, describes using currents having intensity values orders of magnitude larger than can be used with dorsal column stimulation. (Yearwood Declaration, ¶ 28).

Reiss does not describe how or where any electrodes would be implanted, or how the system could be operated using implantable electrodes such that an intensity of the current would

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be within acceptable levels (that do not cause pain) while still providing effective therapy to the patient. (Yearwood Declaration, ¶ 29). In fact, it is untrue that with any application of interferential therapy, electrodes can simply be implanted, and the therapy can be scaled down so that intensity values of the current would be within acceptable levels (that do not cause pain) while still providing effective therapy to the patient. (Yearwood Declaration, ¶ 30).

Based on the disclosure in Reiss, it is unknown if the system in Reiss would work if the electrodes were implanted. For example, Reiss does not describe how to scale down the intensity values of the current within acceptable levels (that do not cause pain) and to still provide effective therapy to the patient. (Yearwood Declaration, ¶ 31).

With the system of Reiss modified to use implantable electrodes, the positioning of the electrodes and the electric field provided by the electrodes would have to be controlled in a way such that the electric field present in the CSF does not spread around the spinal cord. CSF is much more conductive than spinal cord tissue. Thus, if current is not controlled, the current will flow around the spinal cord. Reiss does not describe how to provide this effective therapy to the patient. (Yearwood Declaration, ¶ 32).

C. One of Ordinary Skill in the Art would not modify Reiss in view of Holsheimer

The Examiner stated that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss with electrodes implanted to the dura matter since such a modification would provide the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients." (*Office Action*, p. 6-7). Applicant respectfully disagrees.

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The electrodes as described in Reiss are not the proper type of electrodes for implantation, and thus, one of ordinary skill in the art would not implant the electrodes in Reiss. (Yearwood Declaration, ¶ 33). Similarly, the electrodes in Holsheimer cannot be used with the interferential current system in Reiss because the electrodes in Holsheimer's apparatus generate a field dependent upon configuring the electrodes in a transverse plane, in contrast to configuring the electrodes in a sagittal plane, as shown in Fig. 3 of the present application. (Yearwood Declaration, ¶ 34). Thus, contrary to the Examiner's conclusion on page 7 of the present Office Action, one of ordinary skill in the art would not modify the system of Reiss with electrodes (described within either of Reiss or Holshiemer) to be implanted to the dura matter.

In addition, each of Holsheimer and Reiss is directed to entirely different types of therapy, and one of ordinary skill in the art would not look to Holsheimer's implantable system to improve/modify Reiss's surface interferential system. As evidence, Dr. Yearwood stated that

> As a practicing doctor, I would not modify the system in Reiss to include implantable electrodes so as to provide a possible improvement if the system in Reiss was not providing effective therapy. Reiss is directed to a first stage of physical therapy for back pain (e.g., surface therapy). In contrast, implantable stimulators are only used as a last resort, when all other physical therapy options have been unsuccessful. The difference between use of Reiss' surface stimulator and Holsheimer's implantable spinal cord stimulator amounts to years of treatment, and ultimately, implantation is only used as a last result. The technologies and applications described in Reiss and Holsheimer are thus vastly different.

(Yearwood Declaration, ¶ 35). Implantation is not the next step after failed surface stimulation, and one of ordinary skill in the art would not modify the system in Reiss to include implantable electrodes to improve effectiveness of the system in Reiss. (Yearwood Declaration, ¶ 36).

There simply is no motivation to modify Reiss to include implanted electrodes. Reiss is only concerned with the problem of accommodation, and explicitly describes to place the "frequency signal on a skin surface of a living body". (Reiss, claim 1).

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The Examiner further considered the invention as taught by Reiss in view of Holsheimer to be capable of providing that "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." (*Office Action*, 9.30.10, p. 7). However, the Examiner has not established, as a factual matter, that the system in Reiss modified by Holshiemer would actually be capable of this action. Rejections based on obviousness cannot be sustained with mere conclusory statements. (MPEP § 2142). In fact, Reiss does not describe how or where any electrodes would be implanted, or how the system could be operated using implantable electrodes such that an intensity of the current would be within acceptable levels (that do not cause pain) while still providing effective therapy to the patient. (Yearwood Declaration, ¶ 29). Similarly, Holsheimer does not describe how intensity levels of a modified Reiss system could be operated, and in fact, describes improper electrodes for implantation with the interferential current system in Reiss. (Yearwood Declaration, ¶ 34). Thus, contrary to the Examiner's conclusion on page 7 of the present Office Action, it would not have been obvious to one of ordinary skill in the art to modify the system of Reiss with implantable electrodes as described in Holshiemer.

IV. Response to Examiner's Comments

The Examiner cited to USP 5,466,247 (Scheiner) as evidence that power consumption is reduced through use of implanted electrodes as opposed to surface electrodes. (*Office Action*, 9.30.10, p. 8-9). However, the Carroll Declaration states in paragraphs 6-13 that in SCS, it is necessary to provide deep stimulation for effective pain relief, and that it is desired to provide deep stimulation through the dura mater of the spinal cord while also avoiding spreading of

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stimulation through the cerebrospinal fluid (which would cause pain). With SCS, without a proper current level, deep penetration through the dura mater may not be achieved. Thus, simply implanting electrodes for an alleged reduction in power may not result in effective treatment.

The experiments described in the Carroll Declaration demonstrate that the present application enables one way to provide deep penetration through the dura mater without substantial spreading of the stimulation and resulting side effects. The Examiner has not provided factual evidence that combining the cited references would have the same alleged "predictable" result. Simply reducing power consumption levels may not result in effective treatment.

V. Conclusion

Applicant requests allowance of the claims at this time. Applicant requests the Examiner to call the undersigned at (312) 913-3331 with any questions or comments.

Respectfully submitted,

Date: March 29, 2011

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